UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

MARK GOLDMAN, Plaintiff, v. EXACTECH, INC. and EXACTECH, US, INC. Defendants.	)	Civil Action No.: 1:22-cv-01974 COMPLAINT & DEMAND FOR JURY TRIAL

NOW COMES Plaintiff MARK GOLDMAN ("Plaintiff"), by and through the undersigned attorneys, and bring this action against EXACTECH, INC. ("EXACTECH") and EXACTECH US, INC. ("EXACTECH US") (hereafter collectively as "Defendants"), for personal injuries suffered as a proximate result of the implantation of an Optetrak Comprehensive Total Knee System and alleges as follows:

NATURE OF THE ACTION

1. This is an action for damages relating to Defendants' development, designing, testing, assembling, manufacturing, packaging, monitoring, labeling, preparing, distribution, marketing, supplying, storage, and/or selling of the Optetrak Comprehensive Total Knee System (hereafter as "Optetrak Device"). The Optetrak Device as referred to in this Complaint includes the Optetrak Comprehensive Total Knee System and/or the Optetrak Logic Comprehensive Knee System.

2. Thousands of patients, like Plaintiff MARK GOLDMAN, have been, and/or will be, required to undergo extensive revision surgery to remove and replace defective Optetrak Devices due to a recent recall of these devices in which the Defendants have admitted to failing to properly package the polyethylene insert; a necessary component of the Optetrak Device.

3. As a result of Defendants' failure to properly package the Optetrak Device prior to distribution, the polyethylene liner prematurely degraded and Plaintiff required revision surgeries due to severe pain, swelling, and instability in the knee and leg. These injuries were caused by early and preventable wear of the polyethylene insert and resulting component loosening and/or other failures causing serious complications including tissue damage, osteolysis, permanent bone loss and other injuries.

4. Recipients of the Optetrak Device, like the Plaintiff, have been required to undergo revision surgeries well before the estimated life expectancy of a knee implant and at a much higher rate than should reasonably be expected for devices of this kind.

5. Despite knowledge that the Optetrak Device was defective and resulted in premature failures and accompanying complications, Defendants only first issued a nationwide recall on February 7, 2022 advising the public that "most of our inserts since 2004 were packaged in out-of-specification… vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance."

6. As a direct and proximate result of the defective nature of Defendants' Optetrak Device surgically implanted in Plaintiff which necessitated premature removal, Plaintiff suffered and will continue to suffer serious personal injuries, including pain, impaired mobility, rehabilitation, medical care, loss of enjoyment of life, and other medical and non-medical sequalae.

7. Plaintiff brings this action for personal injuries suffered as a proximate result of

failure of the Optetrak Device. Plaintiff accordingly seeks compensatory and punitive damages, and all other available remedies provided to Plaintiff under the law as a result of injuries MARK GOLDMAN sustained due to the Defendants' negligent, reckless and wrongful conduct.

JURISDICTION & VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and all Defendants.

9. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of New York. At all relevant times Defendants transacted, solicited, and conducted business in New York through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in New York.

10. Venue is proper in this judicial district and division pursuant to 28 U.S.C. § 1391 because Plaintiff MARK GOLDMAN is a resident and citizen of Queens County, New York.

THE PARTIES

11. Plaintiff MARK GOLDMAN is a resident and citizen of Bayside, New York.

12. Defendant EXACTECH, INC. is a domestic, Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

13. Defendant EXACTECH, INC. develops, manufactures, packages, stores, distributes, markets and sells orthopedic implant devices, including Optetrak Devices and related surgical instrumentation throughout the United States, including in and throughout the United States and the state of New York.

14. Defendant EXACTECH, INC. manufactured the Optetrak Device implanted in Plaintiff MARK GOLDMAN.

15. At all times relevant to this action, Defendant EXACTECH, INC. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device in interstate commerce and throughout the State of New York and generated substantial revenue as a result.

16. Defendant EXACTECH US, INC., a wholly owned subsidiary of Defendant EXACTECH, INC., is a domestic Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

17. According to public filings, Defendant EXACTECH US, INC., conducts Defendants' U.S. sales and distribution activities.

18. EXACTECH US, INC. is engaged in the business of designing, developing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing Defendants' products, including Optetrak Devices, into commerce throughout the United States and the state of New York.

19. Upon information and belief, the Optetrak Devices manufactured by Defendant EXACTECH, INC. were distributed by Defendant EXACTECH US, INC. throughout the United States, including in New York, New York where Plaintiff received his implant.

23. At all times relevant to this action, Defendant EXACTECH US, INC., tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device in interstate commerce and throughout the State of New York and generated substantial revenue as a result.

FACTUAL BACKGROUND

24. Upon information and belief, the first Optetrak total knee system was available for implantation in 1994, building upon technology licensed from the Hospital for Special Surgery.

25. At all times material hereto, Defendants designed, developed tested, assembled, selected, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted, and/or sold the Optetrak Comprehensive Total Knee System and the Optetrak Logic Comprehensive Knee System to hospitals in many states, including to the Hospital for Special Surgery in New York, New York.

26. Defendants obtained 510(k) clearance from the Food and Drug Administration ("FDA") for various Optetrak total knee system devices and components between 1994 and 20 17 including under the names: Optetrak, Optetrak Logic and Truliant.

27. 510(k) clearance is distinct from the FDA's pre-market approval ("PMA") process in that clearance does not require clinical confirmation of safety and effectiveness and as such the manufacturer retains all liability for the assertions of safety and effectiveness.

28. 510(k) clearance only requires the manufacturer to notify the FDA under section 510(k) of the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

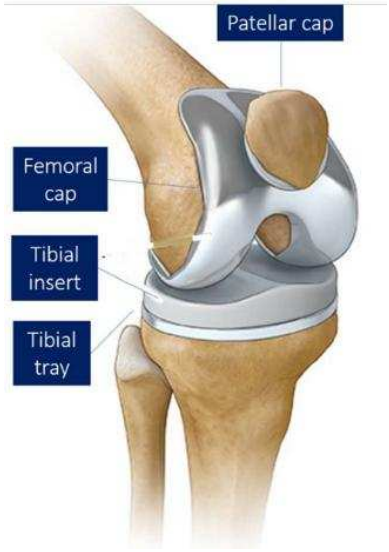
29. All the component parts comprising Plaintiff's Optetrak Device were cleared for marketing by the FDA pursuant to 510(k) process or were marketed without receiving either 510(k) clearance or PMA approval by the FDA.

30. The Optetrak Total Knee System is classified as a knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. It features a mix of polyethylene and metal-based components.

31. According to the Defendants, the device "introduces novel implants and

instruments to make the total knee procedure, easier, faster and more consistent, improving patient satisfaction for a more diverse population requiring total knee replacements."

32. The Optetrak Device is comprised of the following parts: a patellar cap, femoral cap, tibial insert and tibial tray, as shown above. The patellar cap and tibial insert are made of polyethylene.



33. The patellar cap and tibial insert are made of polyethylene.

34. Defendants touted the Optetrak Device as being first-in-class in their product brochures.

35. In their marketing materials, the Defendants promised that the Optetrak Device had excellent long-term clinical outcomes and that "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."

36. Defendants promoted their Optetrak Devices as a system with nearly three decades of clinical success and proven outcomes for patients around the world because of an improved articular design resulting in low polyethylene stresses.

37. However, Optetrak Devices have performed poorly when compared to its competitors. For example, the Australian Orthopaedic Association, a preeminent, internationally recognized orthopedic implant registry, has identified the Optetrak as an implant with a higher-than-expected rate of revision.

38. According to the 2020 Australian National Joint Replacement Registry, the rate of revision for a total knee replacement utilizing an Optetrak tibial component with a Optetrak-CR femoral component was 8.5% at ten years and 10.2% at ten years when implanted with a Opetrak-PS femoral component which far exceeds international guidelines for accepted revision rates.

39. Per the recommendations established by the International Benchmarking Working Group and applied by the Australian Orthopaedic Association, the Optetrak Devices do not qualify for a "superiority benchmark" or even a "non-inferiority benchmark."

40. At all times relevant, Defendants have been aware of a high rate of early failures associated with the Optetrak Device.

41. Upon information and belief, by 2012, Defendants had further clinical evidence that Optetrak Devices were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicate instances of revision due to "loose tibial component", "aseptic loosening", "pain and visible loosening", "polyethylene deformation", "polyethylene worn", and "pain, limited mobility, knee swelling and sensitivity" due to "loose" joint.

42. Upon information and belief, in 2013, complaints continued to be reported. Some examples include revision for "tibial loosening" just two years postoperatively, "revision due to tibial loosening", "during revision, the tibial component was found to be loose and easily removed", "revision of knee component due to loosening", "revision due to pain and loosening."

43. Upon information and belief, the complaints of early onset failures continued in 2014. Some examples include "revision due to tibial loosening", "tibial loosening", "revision of optetrak knee components due to tibial loosening", "revision due to pain and loosening", "revision of optetrak knee components due to aseptic loosening", several reports described as "revision of knee components due to tibial loosening", and "revision of optetrak knee components reportedly due [to] aseptic loosening".

44. Despite Defendants' knowledge of early onset failures of the Optetrak Device, Defendants continued to manufacture, promote, and distribute the Optetrak Device without alerting surgeons or patients of the potential increased risks of early onset failures of the Optetrak Device.

45. Defendants never changed the labeling, marketing materials or product inserts to adequately and accurately warn patients or physicians of the associated increased risks of early failure due to loosening and/or polyethylene wear.

46. It was not until August 30, 2021 did the Defendants take some action and issued a partial recall of all Optetrak All-polyethelene tibial components, including the OPTETRAK All-polyethylene CC Tibial Components; OPTETRAK All-polyethylene CR Tibial Components; OPTETRAK All-polyethylene CR Tibial Sloped Components; OPTERAK All-polyethylene PS Tibial Components; OPTETRAK HI-FLEX PS Polyethylene Tibial Components; OPTETRAK Logic All-polyethylene CR Tibial Components; OPTETRAK Logic All-polyethylene CRC Tibial Components; OPTETRAK Logic All-polyethylene PSC Tibial Components; OPTETRAK Logic Modular PS Tibial Components; OPTETRAK Logic RBK PS Tibial Components; TRULIANT CR Tibial Inserts; TRULIANT CRC Tibial Inserts; TRULIANT PS Tibial Inserts; and TRULIANT PSC Tibial Inserts.

47. In issuing the August 2021 recall, Defendants stated "inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer." *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266

48. According to the FDA website, "Exactech began notification to distributors and sales representatives on about 08/30/2021 via letter titled "URGENT MEDICAL DEVICE RECALL." Actions being taken by Exactech included removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags. This will be performed in a phased approach over the next 12 months. Phase 1 includes immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags. Phase 2 includes, between 05/31/2022 to 08/31/2022, returning all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags." *Id*.

49. Despite initial communications with distributors and sales representatives, Defendants did not issue any communications to surgeons who had implanted Optetrak Device with a recalled polyethylene component or to patients who had received an Optetrak Device with a recalled polyethylene component until months later in February 2022.

50. On February 7, 2022, Defendants issued an "Urgent Medical Device Correction" in which it informed health care professionals that:

> After extensive testing, we have confirmed that most of our inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time,**

> **oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

See https://www.exac.com/wp-content/uploads/2022/02/Exactech-DHCP letter.02.07.2022.pdf

51. The "Urgent Medical Device Correction" went on to further state that Defendants were expanding the recall to include all knee arthroplasty polyethylene inserts packed in non-conforming bags regardless of label or shelf life. The components subject to the recall now included: OPTETRAK®: All-polyethylene CR Tibial Components, All-polyethylene PS Tibial Components, CR Tibial Inserts, CR Slope Tibial Inserts, PS Tibial Inserts, HI-FLEX® PS Tibial Inserts; OPTETRACK Logic®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts, CC Tibial Inserts; and TRULIANT®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts. *Id.*

52. It is estimated that a total of 147,732 inserts implanted in the United States since 2004 were produced with non-conforming packaging. *Id.*

53. Defendants further acknowledged the original Optetrak knee system has shown statistically significant higher overall revision rates compared to other total knee arthroplasties in the Australian, United Kingdom and New Zealand joint registries. *Id.*

54. Specifically, reasons for revision associated with polyethylene wear, including loosening, lysis, and pain, were increased three-to seven-fold with the Opetetrak total knee replacement combination of the Optetrak-PS/Optetrak according to the 2021 Australian National Joint Replacement Registry with revision diagnoses related to accelerated polyethylene wear possibly related to the non-conforming packaging. *Id.*

55. Implanting surgeons were advised to contact patients previously implanted with

recalled components and to schedule an evaluation if the patient is experiencing any new or worsening knee swelling, pain while walking, inability to bear weight, grinding or other noise, instability, or any new symptoms of clicking in the knee. *Id.*

56. Furthermore, Defendants advised surgeons that revision surgery should be considered for patients who exhibit premature polyethylene wear. *Id.*

57. Based on Defendants' own representations, since 2004, Defendants manufactured, promoted, and distributed the Optetrak Device without ensuring the polyethylene components were properly packaged to prevent or minimize oxidation. At no point until August 2021 did Defendants first modify the packaging in an effort to address this defect.

58. At all times relevant to this action, Defendants were aware of the Optetrak Device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery and its attendant complications in patients. Nonetheless, Defendants still did not adequately warn patients, the medical community, or the public about these risks, and continued to promote, market, sell and defend the Optetrak Device until August 2021, at which point in time only a partial recall was issued.

59. At all times relevant to this action, Defendants failed to acknowledge the manufacturing defects in the Optetrak Device due to poor and inadequate quality assurance procedures and due to a wanton and reckless disregard for public safety. Defendants also failed to implement or utilize adequate safeguards, tests, inspections, validation, monitoring and quality assessments to ensure the safety of the Optetrak Device.

60. At the time the Optetrak Device was manufactured and sold to patients, including Plaintiff, the device was defectively manufactured and unreasonably dangerous, and did not

conform to the federal regulations subjecting patients to unreasonable risks of injury.

61. At all times relevant to this action, Defendants' inadequate manufacturing processes also led to material flaws in the quality systems at its manufacturing, packaging, storage and distribution facilities.

62. During the course of manufacturing and distributing the Optetrak Device, Defendants failed in several ways, including, without limitation, by:

a. failing to conduct adequate mechanical testing, including oxygen-resistance or other wear testing for the components, subassemblies, and/or finished Optetrak Device;

b. failing to test an adequate number of sample devices on an ongoing basis;

c. failing to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

d. failing to identify and/or note the significance of any testing that resulted in failure of the Optetrak Device;

e. failing to take corrective actions to eliminate or minimize further failures of the Optetrak Device;

f. failing to adequately explain packaging specifications for the components, subassemblies, and/or finished Optetrak Device;

g. failing to perform adequate quality control before the components, subassemblies, and/or finished Optetrak Device were distributed;

h. failing to pay attention to reports from their sales representatives who reported their observations while attending revision surgeries where

evidence of polyethylene debris and osteolysis was apparent and noted by the surgeons and the sales representatives themselves; and

i. failing to timely implement corrective action and investigations to understand the root cause of these failures while continuing to sell the components knowing they would be implanted into the bodies of thousands of people.

63. On or before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known the Optetrak Device was failing and causing serious complications after implantation in patients. Such complications included, but were not limited to, catastrophic polyethylene wear including the deposition of plastic particulate wear debris throughout the knee, a high rate of component loosening, and overall early system failure resulting in tissue destruction, osteolysis, and other injuries causing severe pain, swelling, instability and dysfunction in the knee and leg necessitating revision surgery.

64. Defendants as manufacturers of orthopedic devices know that each surgery, especially a revision surgery, is always more complicated than an initial knee replacement surgery and is fraught with serious risks of infection, anesthesia errors, dislocations and other serious complications that should be avoided.

65. Defendants, however, ignored reports of early failures of their Optetrak Device and failed to promptly investigate the cause of such failures or issue any communications or warnings to orthopedic surgeons and other healthcare providers.

66. Before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known that the Optetrak Device was defective and unreasonably dangerous to patients, that the product had an unacceptable failure and complication rate, and that the product

had a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

MARK GOLDMAN'S IMPLANT AND REVISION SURGERY

67. On January 17, 2014, Plaintiff MARK GOLDMAN underwent a right total knee replacement surgery and was implanted with an Optetrak Device, including an Optetrak Logic PSC Tibial Insert, size 3.5, 9mm made of polyethylene. Plaintiff's total knee replacement surgery was performed at the Hospital for Special Surgery.

68. Plaintiff was diagnosed with "polymeric-induced synovitis without features of active infection, bulky patella osteolysis where loosening is suspected without displacement, near circumferential bone resorption around the femoral component with severe osteolysis."

69. As a result, he underwent revision surgery of his right knee on February 10, 2022 at the Hospital for Special Surgery.

70. Upon information and belief, the loose components and osteolysis in Plaintiff's right knee was due to premature polyethylene wear of the tibial insert.

71. Following the revision surgery, Plaintiff continues to be limited in his activities of daily living.

72. Despite undergoing revision surgery, Plaintiff experiences daily pain and discomfort in his right knee which limits his activities of daily living and impacts his quality of life.

73. Further, Defendants, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's health care providers the true and significant risks associated with the Optetrak Device.

74. As a direct, proximate and legal consequence of the defective nature of the Optetrak Device as described herein, Plaintiff has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

75. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
STRICT LIABILITY – MANUFACTURING DEFECT

76. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

77. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

78. The Defendants had a duty to manufacture the Optetrak Device in a manner that prevents unreasonable risk of harm or injury to users and patients, including Plaintiff.

79. The Defendants had a duty to distribute, market, and/or sell the Optetrak Device without manufacturing and related packaging defects to prevent an unreasonable risk of harm or injury to users and patients, including Plaintiff.

80. The Optetrak Devices manufactured by the Defendants were not reasonably safe for their expected, intended, and/or foreseeable uses, functions and purposes.

81. The Optetrak Devices were not reasonably safe as manufactured, packaged, distributed, marketed and/or sold by the Defendants.

82. The defects in manufacture of the Optetrak Device were a substantial factor in causing Plaintiff's injuries.

83. At all times herein mentioned, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in manufacture. The defects in manufacture include but are not limited to:

a. failure to package the polyethylene components of the Optetrak Device in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery;

b. the materials used to package the Optetrak Device were of an inferior grade or quality;

c. that the Optetrak Device as manufactured differed from Defendants' intended specifications;

d. that Defendants failed to measure and/or test an adequate number of

samples of Optetrak Devices on an ongoing basis;

e. that Defendants failed to take corrective actions to eliminate or minimize further failures of the Optetrak Device;

f. that Defendants failed to perform adequate quality control or other such testing on the polyethylene inserts used in the Optetrak Device to ensure they complied with required specifications and were not prematurely degrading while stored;

g. failing to select appropriate third-parties to package the polyethylene inserts used in the Optetrak Device;

h. failing to properly supervise and monitor the packaging of the polyethylene inserts used in the Optetrak Device;

i. that Defendants failed to exercise sufficient quality control to ensure the polyethylene inserts in the Optetrak Devices were safe for implantation in users and patients and would not degrade abnormally under average and regular use; and

j. that Defendants violated applicable state and federal laws and regulations; and in all other ways.

84. Defendants knew or reasonably should have known and been aware that the Optetrak Devices were defectively manufactured.

85. The manufacturing defects in the Optetrak Device existed when the device left the Defendants' control.

86. Plaintiff’s physicians implanted the Optetrak Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to

Defendants.

87. The Optetrak Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

88. As alleged herein, Defendants knew or had reason to know that the Optetrak Device caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

89. The manufacturing defects of the Optetrak Device presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

90. The manufacturing defects of the Optetrak Device presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

91. Plaintiff could not, by the exercise of reasonable care, have discovered the manufacturing defect and perceived its dangers or avoided injury.

92. The Defendants are strictly liable for the defective manufacture of the Optetrak Device; the distribution, marketing, and/or sale of the defectively manufactured Optetrak Device; and the injuries sustained by Plaintiff.

93. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical

expenses, and financial losses.

94. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

95. As a direct, proximate and legal consequence of the defective nature of the Optetrak Device as described herein Plaintiff has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

96. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering.

97. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
STRICT LIABILITY – DESIGN DEFECT

98. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

99. Prior to Plaintiff's initial knee surgery, and at all times relevant this action,

Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

100. Defendants had a duty to design and package the Optetrak Device in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

101. Defendants had a duty to distribute, market, and/or sell the Optetrak Device with a design that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

102. The design of the Optetrak Device and corresponding packaging is defective and not reasonably safe for its expected, intended, and/or foreseeable uses, functions and purposes.

103. The Optetrak Device and corresponding packaging are not reasonably safe as designed, distributed, marketed, delivered and/or sold by Defendants.

104. The defective design of the Optetrak Device and packaging received by Plaintiff's implanting surgeon were a substantial factor in causing Plaintiff's injuries.

105. At all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in design. The defects in the design include but are not limited to:

a. that the Optetrak Device has propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well

as the need for revision surgery in patients;

b. failure to design the packaging for the polyethylene components of the Optetrak Device in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery;

c. that the materials used within the Optetrak Device and packaging were of an inferior grade or quality than advertised and promoted by Defendants;

d. Defendants failed to conduct adequate testing, including wear or other testing, on components, subassemblies and/or the finished Optetrak Device as packaged and distributed;

e. Defendants failed to test an adequate number of samples of Optetrak Devices on an ongoing basis;

f. Defendants failed to take adequate steps to specifically identify failure modes with the Optetrak Device with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

g. Defendants failed to identify and/or note the significance of any testing that resulted in failure of the Optetrak Device;

h. Defendants failed to take corrective actions to eliminate or minimize further failures of the Optetrak Device;

i. Defendants failed to adequately design packaging specifications for the

components, subassemblies, and/or the finished Optetrak Device;

j. The polyethylene material used in the Optetrak Device in conjunction with the inferior vacuum bags caused and/or contributed to the devices having a higher failure rate than other similar devices available at the time the Optetrak Devices were put on the market;

k. The polyethylene material used in the Optetrak Device in conjunction with the inferior vacuum bags caused and/or contributed to the devices having a shorter effective lifetime than other similar devices available at the time the Optetrak Devices were put on the market;

l. The Defendants' method of designing the polyethylene insert and packaging increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision surgery; and

m. that Defendants violated applicable state and federal laws and regulations; and in all other ways.

106. Defendants knew or reasonably should have known and been aware that the Optetrak Devices and packaging were defectively designed.

107. The design defects in the Optetrak Device and packaging existed when the device left the Defendants' control.

108. Plaintiff's physicians implanted the Optetrak Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

109. The Optetrak Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or

sold by Defendants reached Plaintiff without substantial change in its condition.

110. As alleged herein, Defendants knew or had reason to know that the Optetrak Device caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

111. The Opetrak Device and packaging as designed carried risks that were outweighed by any utility of the design of the device and packaging because when paired together the implant, the Opetrak Device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Optetrak Device and the packaging in which it was received were in a condition not suitable for proper and intended use.

112. The Opetrak Device and packaging were defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

113. Feasible safer alternative designs providing the same functional purpose were available to the Defendants at the time the Opetrak Device was designed and packaged and offered for sale in the market.

114. For example, Defendants could have utilized vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the polyethylene components from undergoing increased oxidation according to their own admissions.

115. The design defects of the Optetrak Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

116. The design defects of the Optetrak Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

117. Plaintiff could not, by the exercise of reasonable care, have discovered these design defects and perceived its dangers or avoided injury.

118. The Defendants are strictly liable for the defective design of the Optetrak Device; defective design of the packaging of the Device; the distribution, marketing, and/or sale of the Optetrak Device; and the injuries sustained by Plaintiff.

119. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

120. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

121. As a direct, proximate and legal consequence of the defective nature of the Optetrak Device as described herein, Plaintiff has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

122. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and

emotional distress and pain and suffering.

123. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

124. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

125. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

126. Defendants had a duty to provide adequate warnings regarding the Optetrak Device in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

127. Defendants had a duty to distribute, market, and/or sell the Optetrak Device with adequate warnings that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

128. The warnings that accompanied the Optetrak Device and corresponding packaging were defective thereby making the product not reasonably safe for its expected, intended, and/or foreseeable uses, functions and purposes.

129. The Optetrak Device and corresponding packaging are not reasonably safe as labeled, distributed, marketed, delivered and/or sold by Defendants.

130. Inadequate labeling accompanying the Optetrak Device and packaging received by Plaintiff's implanting surgeon was a substantial factor in causing Plaintiff's injuries.

131. At all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective.

132. The Optetrak Device was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the warnings in the instructions for use, operative techniques, directions, marketing and promotional materials, advertisements, white papers, and other communications provided by Defendants or its sales force to physicians and patients with or about the Optetrak Device failed to adequately convey the potential risks and side effects of the Optetrak Device and the dangerous propensities of the device, which risks were known or were reasonably scientifically knowable to Defendants.

133. In particular, Defendants failed to adequately disclose the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, bone loss, osteolysis, and other injuries as well as the need for revision surgery in patients.

134. Defendants consciously disregarded the increased risks of harm by failing to adequately warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Optetrak Device; and continuing to market, promote, sell and defend the Optetrak Device until the very recent recall.

135. Defendants knew or reasonably should have known and been aware that the Optetrak Devices and packaging contained inadequate warnings.

136. The inadequate warnings for the Optetrak Device existed when the device left the Defendants' control.

137. Plaintiff's physician implanted the Optetrak Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

138. The Optetrak Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

139. As alleged herein, Defendants knew or had reason to know that the Optetrak Device caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

140. The Optetrak Device that was labeled, manufactured, distributed, and sold by the Defendants to Plaintiff was in a defective condition that was unreasonably dangerous to any user or ordinary consumer of the device, including Plaintiff.

141. The labeling defects of the Optetrak Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

142. The labeling defects of the Optetrak Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

143. Plaintiff could not, by the exercise of reasonable care, have discovered these defects and perceived its dangers or avoided injury.

144. The Defendants are strictly liable for providing inadequate warnings accompanying the Optetrak Device and packaging of the Device; the distribution, marketing, and/or sale of the Optetrak Device; and the injuries sustained by Plaintiff.

145. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

146. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

147. As a direct, proximate and legal consequence of the defective nature of the Optetrak Device as described herein, Plaintiff has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

148. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering.

149. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
NEGLIGENCE

150. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

151. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

152. Prior to, on, and after the dates of Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants had a duty to exercise reasonable care in testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Optetrak Device for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

153. Prior to, on, and after the dates of Plaintiff's initial knee surgery, Defendants breached this duty and failed to exercise reasonable care and were grossly negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Optetrak Device.

154. At all times material hereto, the Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers associated with the Optetrak Device.

155. Defendants had access to registry data and were aware of complaints that the Optetrak Device caused serious complications including but not limited to polyethylene wear and/or other failure causing serious complications including component loosening, tissue damage, osteolysis, bone loss and the need for revision surgery in patients.

156. Despite the fact Defendants knew or should have known the Optetrak Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Optetrak Device for implantation into consumers.

157. Defendants failed to exercise due care under the circumstances, and their gross negligence and recklessness includes the following acts and omissions:

a. Negligently failing to properly package the polyethylene components of the Optetrak Device;
b. Negligently failing to select appropriate third-parties to package the polyethylene inserts used in the Optetrak Device;
c. Negligently failing to properly supervise and monitor the packaging of the polyethylene inserts used in the Optetrak Device;
d. Negligently failing to properly and thoroughly select the material that would be used in the packaging of the Optetrak Device;
e. Negligently failing to properly and thoroughly select the materials that would be used in the Optetrak Device;
f. Negligently failing to properly and adequately test the Optetrak Device and their attendant parts before releasing the devices to market;
g. Negligently failing to conduct sufficient post-market testing and surveillance of the Optetrak Device;

h. Negligently failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Optetrak Device in accordance with good practices;

i. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Optetrak Device;

j. Continuing to negligently manufacture, and distribute the Optetrak Device after the Defendants knew or should have known of their adverse effects and/or the increased early onset failure rates;

k. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Optetrak Device to consumers, including Plaintiff, without an adequate warning of the dangerous risks of the Optetrak Device;

l. Negligently failing to notify and warn the public, including Plaintiff, and physicians of reported incidents involving injury and the negative health effects attendant to the use of the Optetrak Device;

m. Negligently misrepresenting the safety of the Optetrak Device;

n. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early failure of the Optetrak Device;

o. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early degradation of the polyethylene substance in the Optetrak Device;

p. Negligently failing to exercise due care in the advertisement and promotion of the Optetrak Device;

q. Negligently disseminating information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Optetrak Device;

r. Aggressively promoting the Optetrak Device without proper warnings of the risk of early failure or material degradation in the average user;

s. Aggressively promoting the Optetrak Device even after Defendants knew or should have known of the unreasonable risks from implantation;

t. Negligently failing to warn consumers, doctors, users and patients that the Optetrak Device would contain polyethylene materials not properly packaged and/or in accordance with Defendants' specifications;

u. Negligently diminishing or hiding the risks associated with the implantation of the Optetrak Device; and

v. Negligently violating applicable state and federal laws and regulations; and in all other ways.

158. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Implants, and otherwise distributing the Optetrak Device.

159. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

160. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

161. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, labeling, sale, and distribution of the Optetrak Device, Plaintiff was implanted with the Optetrak Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

162. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, labeling, sale, and distribution of the Optetrak Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering.

163. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

164. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

165. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

166. Defendants owed a duty to orthopedic surgeons, other healthcare providers and to consumers of the Optetrak Device, including Plaintiff, to accurately and truthfully represent the risks of the Optetrak Device. Defendants breached their duty by misrepresenting and/or failing to adequately warn Plaintiff's orthopedic surgeon, the medical community, Plaintiff, and the public about the risks of the Optetrak Device, including the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients, which Defendants knew or in the exercise of diligence should have known.

167. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Optetrak Device knew, or reasonably should have known, that health care professionals and consumers of the Optetrak Device would rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of implanting Optetrak Device.

168. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Optetrak Device knew, or reasonably should have known, that the patients implanted with Optetrak Device would suffer early failure and require revision surgery because the information disseminated by Defendants and relied upon by health care professionals and consumers, including Plaintiff, was materially inaccurate, misleading, or otherwise false.

169. The Defendants failed to exercise reasonable care to ensure that the information

they disseminated to health care professionals and consumers concerning the quality and longevity of the Optetrak Device was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

170. Among Defendants' numerous misrepresentations and misleading omissions are Defendants' assurances that the Optetrak Device was safe, had an excellent performance record, and did not have a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

171. Despite their knowledge of serious problems with the Optetrak Device, Defendants urged their sales representatives to continue marketing the Optetrak Device, and distributed medical literature, white papers, non-peer reviewed studies, and other communications to surgeons in an effort to mislead them and the general public about the risks associated with the Optetrak Device and instead create the image and impression that the Optetrak Device was safe.

172. Defendants made such statements even after they became aware of numerous and serious complications with the Optetrak Device. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data.

173. Defendants made these representations with the intent to induce reliance thereon, and to encourage purchase and implantation of the Optetrak Device.

174. The misrepresentations made by Defendants, in fact were false and known by Defendants to be false at the time the misrepresentations were made.

175. Defendants failed to exercise ordinary care in making their representations

concerning the Optetrak Device and, in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the Optetrak Device.

176. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

177. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

178. As a direct and proximate result of Defendants' acts and omissions, including Defendants' negligent misrepresentations regarding the Optetrak Device, Plaintiff was implanted with the Optetrak Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

179. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including Defendants' negligent misrepresentations regarding the Optetrak Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering.

180. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

181. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

182. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

183. Defendants expressly warranted the Optetrak Devices, including the Optetrak Comprehensive Total Knee System and the Optetrak Logic Comprehensive Knee System, were safe and effective orthopedic devices.

184. Defendants promised that the Optetrak Device had excellent long-term clinical outcomes and that "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."

185. At the time Defendants manufactured, marketed, sold and/or distributed the Optetrak Devices, they knew that the devices were intended for human use, and that Plaintiff was a foreseeable user of the Optetrak Device.

186. The express warranties represented by Defendants were a part of the basis for Plaintiff's use of the Optetrak Device, and he and his surgeon relied on these warranties in deciding to use the Optetrak Device.

187. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Optetrak Devices were to be used and warrantied the same to be in all respects safe, effective and proper for such purpose.

188. The Optetrak Device does not conform to these express representations as demonstrated by the fact that Plaintiff's implant failed prematurely due to polyethylene wear of the tibial insert which necessitated him to undergo revision surgery.

189. At the time Defendants marketed, sold and/or distributed the Optetrak Devices, Defendants expressly warranted that the total knee replacement systems, including all of their component parts, were safe and merchantable for their intended use.

190. Plaintiff and his implanting physician reasonably relied upon Defendants' express warranties.

191. Plaintiff used the Optetrak Device for its intended purpose, and in a reasonable foreseeable manner.

192. The Optetrak Devices manufactured and sold by Defendants, did not conform to Defendants' express representations because the Opetrak Device caused serious injury to Plaintiff when used as recommended and directed.

193. As a direct and proximate result of Defendants' acts and omissions, including breach of express warranty, Plaintiff was implanted with the Optetrak Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

194. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including breach of express warranty, Plaintiff has sustained and will sustain future

damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering.

195. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

196. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

197. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

198. Defendants impliedly warranted, through its marketing, advertising, distributors and sales representatives, that the Optetrak Device was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

199. In fact, the Optetrak Device was not of merchantable quality nor fit for the ordinary purposes and uses for which it was sold and did not meet the expectations of consumers.

200. The Optetrak Device manufactured and supplied by Defendants was not of merchantable quality and was not fit for the ordinary and/or particular purpose for which it was

intended as physicians and patients would expect the components to be properly packaged and stored as to avoid premature degradation of component materials.

201. Plaintiff and/or his physician reasonably relied upon the skill and judgment of Defendants as to whether the Optetrak Device was of merchantable quality and safe for its intended and particular use and purpose.

202. Contrary to such implied warranties, the Optetrak Device was not of merchantable quality or safe for its intended and particular use and purpose, because Defendants failed to package the polyethylene components of the Optetrak Device in vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

203. As a direct and proximate result of Defendants' acts and omissions, including breach of implied warranties, Plaintiff was implanted with the Optetrak Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

204. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including breach of implied warranties, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering.

205. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive

damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a. Judgment in favor of Plaintiff and against all Defendants, for damages in such amounts as may be proven at trial;

b. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, disfigurement, pain and suffering, mental anguish, and emotional distress, in such amounts as may be proven at trial;

c. Punitive and/or exemplary damages in such amounts as may be proven at trial;

d. Attorneys' fees and costs;

e. Interest; and

f. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Dated: April 6, 2022

Respectfully Submitted,

WEITZ & LUXENBERG, P.C.
Attorneys for Plaintiff

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DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury.

Dated: April 6, 2022

Respectfully Submitted,

WEITZ & LUXENBERG, P.C.
Attorneys for Plaintiff

By: /s/ Ellen Relkin, Esq.
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